K100736 SEP 10 2010

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

Date of Application: 2010-07-16

APPLICANT: SMT Schilling Metalltechnik GmbH
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Germany
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CONTACT PERSON: Mr. Erik Schilling
Managing Director
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1. Device Name

Trade Name: Orthopaedic Fixation Pins and Wires / Kirschner / Guide Wires
Common Name: Kirschner Wire (K-Wire)

2. Classification Product Code / Subsequent Code

Our implant system can be classified according following device names and product codes:

Device:	Pin, Fixation Smooth	Pin, Fixation, Threaded
Medical Specialty:	Part 888, Orthopedic	Part 888, Orthopedic
Product Code:	87 HTY	87 JDW
Device Class:	2	2
Regulation Number:	888.3040	888.3040

3. Substantial Equivalence

Orthopaedic fixation pins and wires are substantial equivalent based upon design, dimensional and materials characterization to the Störk Kirschner Wires (K-Wires) and Steinmann Pins (#K030665) of Stork Instrumente GmbH, 78576 Emmingen-Liptingen, Germany and Teleflex KMedic Internal/External Fixation Devices (#K070561) of Teleflex Medical, Bannockburn, IL.

4. Description of the Device

Orthopaedic fixation pins and wires are metal pins for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeleton system.

To ensure the multi-use of these devices, many different models are available. The differences can be as follows:

- Diameter: from 0.6 up to 6.35mm (0.020 up to 0.250 inch)
- Length: from 60 up to 500 mm (2.36 up to 19.69 inch)
- Tips: diamond or trocar Point, round, flat, with or without 3- or 4- shank ends, with or without spherical shape.
- Surface: complete or partial smooth and / or threaded, with or without threading cutter.

5. Intended Use

SMT Schilling's orthopaedic fixation pins and wires are intended to perform as fixation and stabilization unit of bone fractures or as guidance at insertion of implants into the skeletal system.

6. Conclusion

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that SMT Schilling's Kirschner Wires and Pins are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Germany 78570

SEP 10 2010

Re: K100736
Trade/Device Name: SMT Schilling Kirschner/Guide Wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY, JDW
Dated: September 2, 2010
Received: September 7, 2010

Dear Mr. Schilling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Brem

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K100736

510(k) Number: **K100736**

Device Name: SEP 10 2010
SMT Schilling Kirschner/Guide Wires

Indications For Use:

Orthopaedic fixation pins and wires are intended to perform as fixation and stabilization unit of bone fractures or as guidance at insertion of implants into the skeletal system.

Prescription Use _**YES**_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100736